UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,842	10/26/2001	Michel J.N. Cormier	33392-754.201	2394

66956 7590 11/27/2007

WILSON SONSINI GOODRICH & ROSATI & MACROFLUX CORP.
650 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER	
CAMERON, ERMA C	
ART UNIT	PAPER NUMBER
1792	

MAIL DATE	DELIVERY MODE
11/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/045,842	CORMIER ET AL.	
	Examiner	Art Unit	
	/Erma Cameron/	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after t he mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-24,28-35 and 47* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-24, 29-35, 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

"...wherein the coating provides systemic delivery of at least 25% of the agent upon application of the device to the skin of a subject for 5 seconds..." is new matter that was not in the specification as originally filed.

The applicant has pointed to [0061] as support. [0061] is not in the specification that was filed with the USPTO. The examiner assumes that the applicant meant [0045] of the filed specification. [0045] states that 26% of desmopressin was delivered systemically following 5 seconds wearing time. This is much narrower than the statement that has been inserted into every claim (as above), which claims "at least 25%", and is claimed for every agent (drug).

Example 2B ([0045]) involves only one drug, desmopressin. There is no indication that other drugs would meet "at least 25% delivery within 5 seconds".

The applicant is requested to cancel new matter.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szumski et al (3470011).

'011 teaches making a coating of a biological agent such as a vaccine on fine tines that will be used as an intracutaneous injector. The coating is formed by dipping the tines in an aqueous solution of the agent (see Abstract; 1:28-62, 2:38-48; see Examples).

'011 does not teach the details of the size of the tines or the amount of coating, but it would have been obvious to one of ordinary skill in the art to have optimized these parameters because they are known to be relevant to transdermal injection.

'011 does not teach the solubility or viscosity of the agent solution, but because '011 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

5. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer (6537242).

'242 teaches microneedles (10 to 200 microns long) to penetrate the stratum corneum to deliver a dried drug coating of antibiotic, vaccine, protein, etc. (2:39-49; 4:13-5:27; 6:65-7:5; 10:3-1). The needle size overlaps with that claimed by applicant.

'242 does not teach the solubility or viscosity of the agent solution, but because '242 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

6. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell (6589202).

'202 teaches transdermal microneedles (50 to 2000 microns long) with a drug, vaccine, antibiotic, protein, etc. coating (see Abstract; 2:31-41; 4:21-44; 6:36-50; 8:7-46). The needle size overlaps with that claimed by applicant.

'202 does not teach the solubility or viscosity of the agent solution, but because '202 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

7. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/10630.

'630 teaches using microprobes about 10-300 microns long to deliver drugs such as antibiotics, hormone, proteins, etc. into animal epidermal cells. The drugs are applied to the microprobes from an aqueous solution (4:3-15, 9:15-37; 11:24-12:14; 13:4-14; 14:1-8).

'630 does not teach the details of the size of the tines or the amount of coating, but it would have been obvious to one of ordinary skill in the art to have optimized these parameters because they are known to be relevant to transdermal injection.

'630 does not teach the solubility or viscosity of the agent solution, but because '630 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

8. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginaven et al (5457041).

'041 teaches coating microneedles with a coating of proteins or hormones to deliver these agents into animal or plant target cells. This would be inclusive of dermal cells. The coating is formed from an aqueous solution. The needles are 25 microns long and 3 microns wide. The needle size overlaps with that claimed by applicant. (See Abstract; 1:9-18; 3:29-5:15; 7:3-8:39).

'041 does not teach the solubility or viscosity of the agent solution, but because '041 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

9. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cormier et al (US2002 / 010292).

'292 teaches coating stratum corneum-piercing microprotrusion arrays with various agents such as peptides, desmopressin, vaccines etc for transdermal delivery. The microprotrusions are less than 500 micrometers [0009], [0059-[0065].

'292 does not teach the solubility or viscosity of the agent solution used in the coating, but because '292 teaches using agents that are the same as claimed by applicant, these parameters will be the same or similar.

Response to Arguments

10. Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive.

The applicant has argued, regarding all of the above rejections, that none of the references provides guidance to achieve at least 25% delivery within 5 seconds.

All of the references teach application of an active agent to microneedles to produce a dry coating, and all the references teach the same type of microneedles/microprotrusions as claimed by applicant. This would inherently produce delivery systems that would meet the limitations claimed by applicant.

Double Patenting

11. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

12. Claims 18-24, 29-35, and 47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-64 of copending Application No. 11/034,891.

As outlined in the previous office action, although the conflicting claims are not identical, they are not patentably distinct from each other because the Application teaches the limitations of the claims and only fails to teach the dose, solubility, and viscosity of the agent of the instant claims. However, claims in the 11/034,891 application are directed to the same active agents as the claims and specification of the instant application, which would inherently be useful in the same dosage, solubility, and viscosity as instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 18-24, 29-35 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-54 of copending Application No. 10/127108, over claims 21-39 of copending Application No. 10/674626, over claims 10-13 of copending Application No. 10/972231, over claims 33-38 of copending

Application No. 11/201625, over claims 32-34 of copending Application no. 11/206698 and over claims 30-35 of copending Application No. 11/355856.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the coatings on the microprotrusions of the Applications are merely variations of and included in the "pharmacologically active agent" of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. The applicant has asked that the double patenting rejections be stayed until subject matter is indicated to be allowable. This is being done.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Erma Cameron/ whose telephone number is 571-272-1416. The examiner can normally be reached on Monday through Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Erma Cameron/
Primary Examiner
Art Unit 1792

November 23, 2007